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OCT 20 2023 EW

THOMAS G. BRUTON
CLERK, U.S. DISTRICT COURT

LYNARIANE LUCAS

United States District Court
Northern District of Illinois

Plaintiff

v.

(1) BECTON DICKINSON AND Co 'BD PUREWICK CORP
(2) LIBERATOR MEDICAL SUPPLY Co
(3) THE PUREWICK CORP.

Defendant

23-cv-15190
Judge Durkin
Magistrate Judge Finnegan
RANDOM / CAT 2

COMPLAINT(S)

I WANT A JURY TRIAL PLEASE.

(I) PRODUCT LIABILITY CAUSING INJURY AND DEATH BY A DEFECTIVE MEDICAL OR PHARMACEUTICAL PRODUCT 'THE PUREWICK EXTERNAL FEMALE CATHETER SYSTEM' (HOME USE DEVICE) + ALSO USED IN HOSPITALS

(II) PRODUCT DESIGN DEFECT

(III) FAILURE TO WARN / DEFECT IN MARKETING

(IV) PUBLIC SAFETY HAZARD

INCREASED RISK FOR others to BECOME INFECTED WITH USE AND POSSIBLY DIE AS A CONSEQUENCE.

NOTABLY: OTHERS USING IT AT HOME (vs Hospital use) + WITHOUT ACCESS to IMMEDIATE MEDICAL + PHYSICAL + LABORATORY MONITORING AVAILABLE AND THOSE LESS EDUCATED FOR SIGNS OF INFECTION + CONTAMINATION

(V) FAULTY INSTRUCTIONS FOR USE

(PLEASE SEE ATTACHED SHEETS)

LynAriane Lucas 10/20/2023

[If you need additional space for ANY section, please attach an additional sheet and reference that section.]

TITLE: Health Care / Pharmaceutical – Personal Injury Product Liability: Description – Action alleging personal injury or death caused by a defective medical or pharmaceutical product. (Torts Code: #367) (Plaintiff: LynAriane Lucas)

Visible Contamination Incident #1:
PureWick Catheter isolated from
Sept. 17, 2021; Emergent Hospitalization of mother with admittance Sept. 22 – Oct 1, 2021.

Visible Contamination Incident #2: PureWick Catheter isolated from Oct. 16,2021; Emergent Hospitalization of mother on Oct. 22, 2021 and DEATH of mother in the ER.

Plaintiff: LynAriane Lucas

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS

Vs

Defendant(s):

1. Becton Dickinson and Co 'BD PureWick Corporation'
2. Liberator Medical Supply company
3. The PureWick Corporation

COMPLAINT

Jurisdiction: 28 U. S. C. 1331 & 1332

FACTS

My mother used the PureWick External Female Catheter system at home since end March of 2021. Sometime afterwards her physical health and mentation began to decline precipitously with its use for her urinary incontinence. She became noticeably lethargic and confused unlike anything she had ever exhibited prior to the use of the PureWick system. TWO incidents of noticeably visible 'WICK' contamination on September 17, 2021 and October 16, 2021 **(photos provided)** – she required TWO emergent ambulance transported hospitalizations on September 22, 2021 (she was admitted 09/22/21 – 10/01/21) and October 22, 2021 (when she died).

I claim that the WICKS facilitated the growth of several species of fungi and bacteria (as tested and proven by the 'PureWick company' and an independently hired laboratory 'Accugen Lab' which led to her becoming infected and septic and onto events which caused her injuries, severe suffering and death.

We acquired the system to help with her urinary incontinence after I saw it advertised on many numerous occasions at various times throughout the day on various television channels as the safe and reliable system to use in one's home for "moderate to severe urinary incontinence" in women. It promised also "relief from nighttime trips to the bathroom" interpreted as a safety measure to also prevent falls in the elderly (as the commercial had an elderly woman using the device).

The PureWick device is presently owned by the BD (Becton Dickinson Company – purchased from PureWick) and is made, marketed and distributed by Becton Dickinson & Liberator Medical Supply Company. As stated by the company in a lawsuit Case # 19-1508- MN 'PureWick versus Sage' – PureWick claimed below:

"PureWick developed and patented a groundbreaking female external catheter, the PureWickTM FEC Solution. PureWick's female external catheter provides an incontinence

solution for women, ***designed to reduce catheter-associated urinary tract infections ("CAUTI")*** *and skin damage caused by urine-soaked diapers and bedding."*

It is also noted according to that lawsuit that:

"PureWick has received industry recognition for its innovation of the PureWick technology, including MedTech Dare to Dream Design Challenge (Finalist, 2014); Most Innovative New Product Award, Medical Devices and Pharmaceutical Products Category (Winner, 2015, connect.org); Athena Pinnacle Award (Winner, 2016)."

The company advertises for the device's use; in pamphlets, online, television commercials, etc. for use in the elderly, debilitated patients, hospice patients, etc. with moderate to severe urinary incontinence. Their promise to reduce 'CAUI' in articles that are supported by shareholders in their company. In contradiction to that claim; articles published of two hospital studies in peer reviewed medical journals **(referenced below)** proved that the device increased urinary tract infections in hospitalized patients (#350 pts) 3x more than the standard 'indwelling' urinary catheters. The PureWick company and affiliates claim in product promotion campaigns - that there is a decrease in urinary tract infects in comparison to the standard indwelling catheters.

Company associated articles directly imply the 'external' PureWick Catheter device is superior for safety against UTI's and hence potential sepsis and death.

My mother was injured, suffered, and died as a direct consequence of the PureWick Catheter Device.

THE PRODUCT DESIGN DEFECT: is faulty as the 'WICK' material serves as a growth culture medium (there is nothing to stop the growth or prevent the growth of bacteria or fungi).

The SHAPE of the device (by design) allows the direct contact of microscopic fecal contaminants to travel from the anus to the vaginal opening (as the wick covers both openings allowing a direct conduit for contamination transfer) in a warm moist environment during the vacuum capture of urine. The device is vacuumed suctioned within the labia of the woman's vagina and within 8 – 12 hours (the time instructed by the company to allow placement until changing with a new one "unless soiled with feces, etc.") – the WICK grew enough contamination that it became highly visible to the naked eye (photos included). Note: I changed the device strictly as instructed and adhered to the instructions provided by the company precisely and consistently.

This direct growth and spread of contaminants (bacterial and fungal) allowed seeding through my mother's vaginal mucosa and into her bloodstream and throughout her body which caused

urinary tract infection (s) and sepsis – culminating in inflammatory / infectious vascular thrombosis of her veins in her pelvis in proximity to the urinary bladder, sepsis associated delirium and her death. The contaminants isolated on the WICKS was consistent to those found in her urine. ANALYSIS IN THE HOSPITAL URINARY INFECTION IS NOTED THROUGHOUT HOSPITAL RECORDS AND ON DEATH CERTIFICATE

FAILURE TO WARN / DEFECT IN MARKETING – that this detrimental and deadly consequence could occur by design and by the company's how to USE instructions. The device grew visibly confluent contaminants in less time than the company's instruction for standard changing (every 8 – 12 hours).

THERE WAS ALSO INCREASE RISK AND LIMITATION TO RESOURCES DUE TO COVID PANDEMIC

I would never have used the device had I known that the PureWick catheter would allow the growth and culture medium for contamination – that caused my mother to suffer extensively from infection and sepsis – and ultimate death on October 22, 2021 at 6:40 p.m. despite aggressive and invasive resuscitation efforts at The Little Company of Mary OSF Hospital, Evergreen Park, Illinois.

I contacted the company (via telephone and email) after Incident #2 (10/16/2021) on October 17, 2021 – 5 days before my mother's death on October 22, 2021.

STATING MY CONCERN FOR THE GENERAL PUBLIC USING THIS SYSTEM: HAZARD TO OTHER USERS.

(I have the email proof) stating in an email - that I isolated a contaminated Wick and that I was concerned for other users of the system. I kept the wicks from Sept 17, 2021 and October 16, 2021 in the freezer. I ceased my mother's use of the PureWick on October 16, 2021 – as the contamination was too blatantly obvious and the correlation of her previous hospitalization (on Sept 22, 2021 – October 1, 2021) - became apparent as to the DIRECT causation – the PureWick Catheter System. HOME USERS MAY NOT RECOGNICE CONTAMINATION OF WICKS.

Note: NOTE: HOME USERS ARE LAY PEOPLE (General public) AT HOME WITHOUT ACCESS TO HOSPITAL RESOURCES AND TESTING OR INTERVENTION (INCREASES RISK FOR HARM)

In a questionnaire (and in referenced emails, etc.) the company asked my mother's age and pre-existing conditions.

Age discrimination – as the device is specifically advertised towards the elderly. THIS contradicts to whom the DEVICE IS TARGETED

Pre-existing conditions – my mother had none that would cause her to have increased infections. Additionally, the company advertises in articles found – to be used for hospice and debilitated patients.

Race: the questionnaire inquired into 'race' which I hesitantly answered as Native / African American – Race is not a risk factor for urinary tract infections and sepsis.

I felt the company disregarded my mother's precious life as not mattering. Their actions and lack of action proved so. I cannot discount that also possibly Age and Race played a factor as well. My mother's life mattered. My life matters.

My mother was very important to me and her passing have left a large and unfillable void in my life. I have suffered greatly witnessing her suffer and die. I watched the resuscitation efforts and I have relived the events surrounding her suffering and death every night for the past 2 years.

Reference Articles; Implicating the PureWick Catheter System as causing INCREASED Urinary Tract Infections -

A single institution pre-/post-comparison

after introduction of an external urinary

collection device for female medical patients

Nathan Jasperse1 •, Oscar Hernandez-Dominguez2

Jacob S Deyell3 •, Janani P Prasad3

, Charlene Yuan, Meril Tomy3, Catherine M Kuza4, Areg Grigorian3 and Jeffry Nahmias3

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jip.sagepub.com

Effect of external urinary collection device

implementation on female surgical patients

Melinda Lem a, Nathan Jasperse a,b, Areg Grigorian a,c, Catherine M. Kuza d, Jacob Sahag Deyell a, Janani Pankajam Prasad a, Charlene Yuan a, Meril Tomy a, Jeffry Nahmias a,

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